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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

WEBER, JON P

ART UNIT PAPER NUMBER

1651

DATE MAILED: 08/29/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/888,824

Applicant(s)

PERRIER ET AL.

Examiner

Jon P Weber, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 44-65 is/are pending in the application.
- 4a) Of the above claim(s) 65 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 44-64 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 11 6) ☐ Other:

Status of the Claims

The response with amendments filed 16 June 2003 has been received and entered. Claims 44-65 have now been presented for examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

Newly submitted claim 65 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The originally claimed method is a screen for compounds potentially active in the field of "lipolysis". Claim 65 is a method of evaluating effectiveness of a slimming care or treatment. While the original claims describe how to go fishing for suitable compounds for lipolysis, the newly submitted method requires that a suitable compound is already at hand is being evaluated for effectiveness in a real-world use.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 65 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 112

Claims 44-64 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for testing in the presence and absence of inhibitor and

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comparison to a second inhibitor, does not reasonably provide enablement for comparison to absence **or** a second inhibitor. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and or use the invention commensurate in scope with these claims.

As remarked in the Office action of 15 January 2003, there are three possible comparison outcomes: 1) $U < K$; 2) $U = K$; and 3) $U > K$, where U = activity in presence of unknown, and K = activity in presence of known inhibitor. Because the claims do not require **both** comparisons, the nature of the inhibitory nature of the test substance is indecisive for the reasons of record.

Claims 54-55 and 57 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 54 recites "an inhibitor" in step a, which lacks antecedent basis.

Claim 57 is very confusing in the last three lines. The terms "positive or negative activity" lacks antecedent basis.

Claim Rejections - 35 USC § 103

Claims 44-64 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Cook et al. (US 5,855,917), Wagle et al. (US 6,326,396), Takahashi et al. (US 5,955,072), Takeda et al. (US 5,244,798), Vainio et al. (1982), Cheng et al. (1990), Carroll et al. (1992) and Bensadoun et

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al. (1974) in view of NEFA-C kit from Wako in view of NEFA-C Kit Instructions and Kikuchi et al. (US 4,301,244).

It is argued that the claims as amended require monitoring "using an enzymatic technique on the reaction medium". It is urged that Takeda et al. only disclose using the NEFA-C kit on an isopropanol extract of the reaction medium and that a person of ordinary skill in the art would expect that the proteins in the reaction medium would interfere with the enzymatic assay.

The NEFA-C Kit Instructions clearly indicate that the enzyme used to detect free fatty acids (FFAs) is acyl-CoA synthetase (ACS). The reaction is monitored at 550 nm. The kit is designed to be used in determining FFAs in serum and control serums are also available. Clearly, the enzyme is not interfered by the kinds of proteins that would be in the instant reaction medium. Serum contains albumin as a major component. It would appear that the NEFA-C kit is based upon Kikuchi et al. (US 4,301,244). Kikuchi et al. clearly indicate that the method is designed to overcome problems of measuring FFAs in serum in particular. Hence, there is no reason to believe that a person of ordinary skill in the art would avoid using the NEFA-C assay method on the reaction medium as argued in the response. It would seem that Takeda et al. are performing the extraction to assure that the reaction with lipoprotein lipase has been fully quenched. This avoids the problem of continued formation of FFAs during the assay for FFAs. A person of skill in the art of kinetics knows that a reaction rate can be monitored in one of three ways: 1) the extent of reaction in a fixed amount of time, 2) the time it takes to achieve a fixed amount of reaction, or 3) continuous monitoring of the extent of reaction. Scenarios 1 and 2 are endpoint assays. Scenarios 1 and 2 can be used to approximate scenario 3 by using a series of endpoints. In the instant case, the assay of lipoprotein lipase is practiced by coupling the endpoint of type 1

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or 2 with the determination of FFAs in that step by ACS measurement. The ACS assay is a quantitative assay of FFA as opposed to a kinetic assay. From the perspective of the ACS reaction, all that matters is how much FFA is present. Quenching the reaction is tantamount to scenario 2. Whether extracted or not, the amount of FFA is fixed by the quench. It is then quantitated by ACS in the NEFA-C assay.

Applicant's arguments filed 16 June 2003 have been fully considered but they are not persuasive. The rejection under 35 U.S.C. 103 is adhered to for the reasons of record and the additional reasons above.

No claims are allowed.

Other references cited by examiner but not relied upon are cited to establish the state of the art and inherent properties of ACS.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

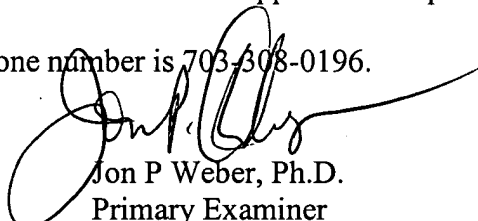
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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon P Weber, Ph.D. whose telephone number is 703-308-4015. The examiner can normally be reached on daily, off 1st Fri, 9/5/4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 703-308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Jon P Weber, Ph.D.
Primary Examiner
Art Unit 1651

JPW